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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

HM12/0427

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ART UNIT

PAPER NUMBER

1642

16

DATE MAILED:

04/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/897,441

Applicant(s)

Fibl et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7, 9-12, and 14-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7, 9-12, and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Response to Arguments

1. Claims 5-7, 9-12 and 14-23 are pending and under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Withdrawn

3. The rejection of claims 5-7, 9-12 and 14-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention is withdrawn.
4. The rejection of claims 5, 12 and 23 under 35 U.S.C. 102(b) as being anticipated by Sytokowski et al (USP 4, 590,168) is withdrawn.

New Claim Rejections

5. Claims 5, 6, 7, 9-12 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and 6 recite "EPO peptide consists essentially of a peptide ...". It is unclear how "consists essentially of" differs from 'consists of' or 'comprises'.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 17-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies directed against an erythropoietin peptide selected from the group consisting of P2 and P2/1, wherein said antibody neutralizes the biological activity of EPO,

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does not reasonably provide enablement for antibodies which are directed against epitopes of EPO which bind the EPO receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are drawn to anti-EPO antibodies directed against epitopes of EPO which bind to the EPO receptor. The specification describes the generation of antibodies which neutralize the activity of EPO by the immunization of animals with EPO derived peptides P2 or P2/1. The specification does not teach a screening method for antibodies, whereby one of skill in the art could differentiate between antibodies which neutralization of EPO activity and antibodies which bind to epitopes of EPO which, without the presence of said antibody, would bind to the EPO receptor. The specification does not demonstrate a mechanism whereby the binding of neutralizing antibodies to EPO would not bind epitopes of EPO which were responsible for receptor binding. Sytkowski et al (Journal of Biological Chemistry, 1987, Vol. 262, pp. 1161-1165) disclose antibodies raised against peptides 99-118 and 111-129 of EPO which neutralized the action of EPO. Sytkowski et al suggests that these peptides represented the receptor binding domain of EPO, and therefore this neutralizing activity exhibited by antibodies directed to these peptides is due to interference in the binding of EPO to its receptor. As the specification does not teach how to discern between neutralizing EPO antibodies and antibodies which bind to epitopes of EPO responsible for the binding of EPO to the EPO receptor, one of skill in the art would be subject to undue experimentation in order to practice the invention.

8. Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sytkowski et al. ^{I.D.S. of Paper No. 4} (Journal of Biological Chemistry, 1987, Vol. 262, pp. 1161-1165). Claims 17 and 18 are drawn to an anti-erythropoietin antibody directed against an epitope of EPO which bind to the EPO receptor and neutralizes the biological activity of EPO. Sytkowski et al discloses two antibodies directed against peptides 99-118 and 111-129 of EPO which were able to neutralize

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the activity of EPO. As the specification is not enabling for the discernment between neutralizing antibodies and antibodies which bind to EPO epitopes responsible for the binding to the EPO receptor, all embodiments of claims 17 and 18 are disclosed by Sytkowski et al.

9. All other rejections and objections as stated in Paper No: 14 are withdrawn.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

April 22, 2001